

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

REC'D 16 FEB 2005

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year) **14 FEB 2005**

Applicant's or agent's file reference

FOR FURTHER ACTION

See paragraph 2 below

386/04133

International application No.

International filing date (day/month/year)

Priority date (day/month/year)

PCT/US04/25238

04 August 2004 (04.08.2004)

04 August 2003 (04.08.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61B 1/00 and US Cl.: 600/121

Applicant

VISION-SCIENCES, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US

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Commissioner for Patents
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**WRITTEN OPINION OF THE
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Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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Box No. II Priority

1. ☐ The following document has not yet been furnished:

☐ copy of the earlier application whose priority has been claimed (Rules 43*bis*.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rules 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority has been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

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Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|---|-----|
| Novelty (N) | Claims <u>9,22,28,51-56,61,62,66</u> | YES |
| | Claims <u>1-8,10-21,23-27,29-50,57-60,63-65,67-72</u> | NO |
| Inventive step (IS) | Claims <u>9,56,66</u> | YES |
| | Claims <u>1-8,10-55,57-65,67-72</u> | NO |
| Industrial applicability (IA) | Claims <u>1-72</u> | YES |
| | Claims <u>NONE</u> | NO |

2. Citations and explanations:

Please See Continuation

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

V. 2. Citations and Explanations:

Claims 1-8,12-16,19-21,23-24,27,29-34,36-50,57-60 and 67-72 lack novelty under PCT Article 33(2) as being anticipated by U.S. Patent No. 5,025,778 to Silverstein et al. Silverstein et al. disclose a tubing having a radially flexible wall coupled to said insertion tube, wherein the tubing has a variable cross-sectional area and is capable of providing a potential channel in an endoscope insertion. Silverstein et al. disclose a device for selectively stiffening a portion of the insertion tube while it is being inserted into the body or after it has been inserted into the body. The tubing is sufficiently flexible to be totally collapsed so that its cross-sectional area is approximately that of the wall of the tubing. The channel of the tubing is radially expandable to provide a lumen sufficiently large for matter to pass therethrough. The channel extends along an insertion tube into the body to permit medical devices to pass therethrough and to the body. A plurality of such flexible tubings, each having a respective channel, may be positioned around the outer circumference of the insertion tube. Furthermore, Silverstein et al. disclose numerous methods or devices may be used to expand the tubing. A rigid (but flexible) rod may be insertable into the channel to expand the tubing. A noncollapsible tubing may be carried by the rod into the flexible tubing and remain in the flexible tubing to prevent it from collapsing after the rod is removed. Any selected medical device may then be passed through the tubing to the tip of the endoscope for medical uses. In one embodiment, a plurality of flexible tubings are provided around the insertion tube to permit a plurality of medical devices to extend through the tubings simultaneously for use in a cooperative relationship. Alternatively, the flexible tubing may be expanded by forcing fluid under pressure into the tubing. The bending characteristics of the insertion tube may be changed by inserting a rod into the tubing a selected length. Alternatively, the bending characteristics of the insertion tube may be varied by pumping a fluid under a selected pressure into the tubing over a selected length or portion of the insertion tube. This can be the entire length. The proximal portion (close to the examiner) or another portion of the insertion tube closer to the tip may be selectively stiffened without stiffening either the proximal or distal tip (see Cols. 2-3 and Figs 1-6).

Claims 1-7,13-16,23-24,27,32 and 33-34 lack novelty under PCT Article 33(2) as being anticipated by U.S. Patent No. 5,503,616 to Jones. Jones discloses a smaller scope to gain access to a body cavity. Once access has been gained it is usually a simple procedure to dilate the cavity or orifice to allow entry of larger instruments or devices. The endoscope includes an elongated, substantially cylindrical portion having a first distal end and a second proximal end. The channel system comprises a collapsible channel with a first distal end and a second proximal end and is adapted to extend alongside and exterior to the cylindrical portion of the endoscope. The collapsible channel is provided with an access means communicating between the first end and the second end of the collapsible channel. The system also includes a means to attach the collapsible channel to the endoscope. Further, the collapsible access channel of the present invention provides a means to allow more and/or larger instruments to be placed in a body cavity. An endoscope with the attached access channel in collapsed form is first inserted into the body orifice. After insertion an instrument, generally in the form of a tube or a biopsy mechanism, may be inserted into the access channel. As the instrument is moved along the access channel, the elasticity of the channel enables the channel to enlarge and conform to and fit the instrument. The body orifice also naturally dilates to conform to the enlarged access channel. The collapsible channel, therefore, provides a variable sized entrance into the body orifice depending upon the medical procedures that are required see Col. 3, Line 22 - Col 4, Line 36).

Claims 1-6,10-11,24-26,31 and 33-36 lack novelty under PCT Article 33(2) as being anticipated by U.S. Patent No. 6,461,294 to Oneda et al. Oneda et al. disclose an apparatus and methods for attaching and forming enclosed inflatable members on an endoscope

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

assembly with a disposable sheath. A flexible and resilient cuff member is positioned on the outer surface of the disposable sheath and sealably and fixedly bonded to the sheath cover material at the cuff edges to form an annular space capable of inflation. The inflatable member formed thereby is inflated through a lumen internal to the sheath that has an opening into the interior annular space. In another aspect, the annular space may be divided into separate inflatable lobes. In still another aspect, the cuff member is a flexible and resilient enclosed member that is substantially toroidal in shape that is positioned on the outer surface of the sheath. In a further aspect, the inflatable member is formed from an excess length of sheath cover material disposed on the disposable sheath. A single reentrant fold of sheath material is formed with an edge that is sealably and fixedly bonded to the sheath cover material to form an annular space capable of inflation. In alternate aspects, the excess length of cover material may be used to form members with dual reentrant folds that comprise inflatable members with single and dual inflatable lobes (see Col. 2, Line 52 - Col. 3, Line 7 and Col. 5, Line 38-67).

Claims 1-6, 17-18, and 63-65 novelty under PCT Article 33(2) as being anticipated by U.S. Patent No. 6,761,685 to Adams et al. Adams et al. disclose a controllable sheath for use with an endoscope. Adams et al further disclose a stiffening member that may include sheath guide 60, 61 fixedly disposed to the outside of endoscope 30 and adjacent to lumen 53, 54. As best shown in FIG. 6A, sheath guide 60, 61 is configured to engage with guide pin 64, 65 (see Col. 9, Lines 4-24).

Claims 22, 28, 51-55, and 61-62 lack an inventive step under PCT Article 33(3) as being obvious over U.S. Patent No. 5,025,778 to Silverstein et al. in view of U.S. Patent No. 6,385,200 to Grossi. Silverstein et al. disclose a sheath apparatus having a channel for use with an endoscope but is silent with respect to placing an electrode is mounted on an external surface of the channel tube. Grossi teaches of an analogous device having an electrode 18 and an electrode guide channel 68 wherein the device is capable of coagulation techniques well known in the art (see Col. 3, Lines 20-65). It would have been obvious to one skilled in the art at the time the invention was made to mount an electrode on the sheath of Silverstein et al. in order to provide a coagulating tool which is readily cheap, disposable and easy to use as taught by Grossi and is well known in the art.

Claims 1-72 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.